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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,640	03/20/2002	Stephen Anthony Burbidge	PG3733USW	5949

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EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,640

Applicant(s)

BURBIDGE ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/10/04 & tele. interview on 4/28/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 04202004.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

- I. The objection of claim 14 will not be maintained in light of the amendment.
- II. The rejection of claim 14 under 35 USC 112, first paragraph, will be maintained for the reason of the record.
- III. The rejection of claim 14 under 35 USC 102(b) will not be maintained in light of the amendment.
- IV. The applicant's amendment necessitated a new ground of rejection(s) in this Office action.

Status of Application

1. By Amendment filed January 10, 2004, Claims 1-14 have been cancelled and Claims 15-16 have been newly added.
2. Newly submitted or amended claims 15-16 are directed to an invention that is independent or distinct from the invention originally claimed invention.

It is noted that applicant originally has received an action on the merits for the originally presented invention which is directed to a method of treating "neurotransmission disorders, CNS disorders, functional disorders, neurodegenerative diseases or tinnitus..." retigabine in claim 14. The search of "linopiridine" nor "the treatment of muscle relaxation, fever reduction, anxiolytic" was not included in the original examination, as being directed a non-elected invention.
3. A telephone call was made to Bonnie L. Deppenbrock on April 29, 2004 to discuss the newly added claims 15 and 16, particularly to newly added subject matters of

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the claims, "linopiridine", "non-inflammatory pain" and "the treatment of muscle relaxation, fever reduction, anxiolytic".

The agreement was made that "linopiridine" is withdrawn from further consideration as being directed a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Furthermore, the agreement was made to include the examiner's search to "muscle relaxation" in this Office action (as the elected species) and make this Office action as Final Office action.

Election/Restrictions

4. This application contains claims directed to the following patentably distinct species of the claimed invention: "non-inflammatory pain", "muscle relaxation", "fever reduction", "anxiolytic", "functional bowel disorder", "tinnitus", "ophthalmic disease" or "tolerance to a dependence inducing agent".

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. During a telephone conversation with Bonnie L. Deppenbrock on April 29, 2004 a provisional election was made to prosecute "muscle relaxation" as the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claim 15 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As discussed above, the examination in this Office action is restricted to the elected species, "muscle relaxation".

New Matter

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7. The amendment filed January 10, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “non-inflammatory pain”.

Applicants state that the newly added claims are based on original claims 2, 4, 6 and 8 as well as the application at page 1, line 6 and line 25. However, no support can be found for “non-inflammatory pain”.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 16 is rejected under 35 USC 112, first paragraph, because the specification while being enabling for treating seizure or inflammatory pain, does not reasonably provide enablement for the treatment of “functional bowel disorders, tinnitus, ophthalmic disease or the prevention or reduction of tolerance to a dependence inducing agent”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is analogous to the original rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites “A method for the treatment of muscle relaxation, fever reduction, anxiolytic”. It is not clear whether the administration of retigabine provides a ultimate therapeutic effect of providing muscle relaxation, fever reduction or anxiolytic or treating a patient suffering from muscle relaxation, fever reduction or anxiolytic. It appears that applicants’ attempt to combine the method which requires “producing muscle relaxation, fever reduction or anxiolytic” with the method which requires “treatment of functional bowel disorder, tinnitus, ophthalmic disease or the reduction of tolerance to a dependence..” renders the definition of the subject-matter of said claim unclear.

For the examination purpose, the claim 11 is interpreted as “a method of producing muscle relaxation, comprising retigabine as a KCNQ2/3 potassium channel opener”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Kapetanovic et al. (CNS Drug Reviews, 1996, 2/3, pp. 308-321).

Kapetanovic teaches that the administration of D-23129 (retigabine) in animals produces muscle relaxation.

Conclusion

11. Applicant's amendment necessitated a new ground of rejection(s) in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

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Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

A handwritten signature in cursive script, appearing to read "Zohreh Fay", is written below the printed name and title.